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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,775	09/12/2003	Raymond J.H. Westheim	SYN-0032	5762

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MARK R. BUSCHER
SYNTHON IP INC
7130 HERITAGE VILLAGE PLAZA
STE 202
GAINESVILLE, VA 20155

EXAMINER	
SHIAO, REI TSANG	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/660,775	Applicant(s) WESTHEIM, RAYMOND J.H.	
	Examiner Robert Shiao, Ph. D.	Art Unit 1626	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED on June 30, 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *1-10*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *14-22*.
   Claim(s) withdrawn from consideration: *23-28*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

/kamal saeed/

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

R. S. 7/19/06

Continuation of 11. does NOT place the application in condition for allowance because:

Responses to Amendment/Arguments

1. Amendment of claims 3 and 8, and cancellation of claims 11-13 and 29 in the amendment filed on June 30, 2006, is acknowledged. Claims 1-10 and 14-28 are pending in the application.

2. Since the IR or X-ray diffractogram has been incorporated into claim 3 or 8 respectively, therefore, the rejection of claims 3 and 8 under 35 U.S.C 112, second paragraph, has been overcome in the amendment filed on June 30, 2006. Since claim 11 has been canceled, therefore, the rejection of claim 11 under 35 U.S.C. 112, second paragraph, has been obviated herein.

3 Applicant's arguments regarding the rejection of claims 1-10 and 14-22 under 35 U.S.C. 102(a) or 103(a) over Ekwuribe's US 6,583,306, have been fully considered and they are persuasive. The melting point (i.e., 178 degrees) of Ekwuribe's bicalutamide compound is distinct from the instant melting point (i.e., 192.4 degrees) of the instant form II of bicalutamide compound. Therefore, the rejection of claims 1-10 and 14-22 under 35 U.S.C. 102(a) or 103 (a) over Ekwuribe's US 6,583,306, has been withdrawn.

4. Applicant's arguments regarding the rejection of claims 14-22 under 35 U.S.C. 102(b) or 103(a) over Tucker's US 4,636,505, have been fully considered but they are not persuasive. It is noted that Tucker's 505 disclose same compositions comprising the same instant compound bicalutamide. It is well recognized in the art that process of preparing pharmaceutical composition will produce the thermodynamically stable form of crystals, thus, Tucker's crystal form and instant form II, after mixing, grinding, compressing would both be transformed into the same thermodynamically stable form(s) of the instant claimed compound, also see Brittain's publication, polymorphism in Pharmaceutical Solids, Drugs and the Pharmaceutical Science; 1999, V. 95, pages 348-361.

To demonstrate unobviousness from Tucker's compositions, applicants must show unexpected result stemming from the instant crystalline form over the crystalline form of Tucker's in form of distinct form(s) or mechanical advantage(s) of the instant crystal over the crystal of Tucker's, see Ex parte Conn and Norman, 119 USPQ 388 (1956), also see In re Grose & Flanigen, 201 USPQ57. Alternatively, applicants are requested to provide a side-by-side comparison between the instant compositions comprising form II and Tucker's compositions comprising form I, wherein the crystalline form II of the instant composition is thermal stable and having original characteristics (i.e., X-ray diffraction) after processes of grounding, mixing and compressing. The rejection of claims 14-22 under 35 U.S.C. 102(b) or 103(a) over Tucker's US 4,636,505, is maintained.

5. Applicant's arguments regarding provisional rejection of 14-22 under the judicially created doctrine of obviousness-type double patenting over claim 1 or 11 of Ortega et al. co-pending application No. 10/842,632, see US 2005/000,869 A1, have been fully considered but they are not persuasive. A terminal disclaimer is requested to file to the Office to overcome the rejection.

6. Claims 14-22 are objected. Amendment of claims 14-22 as a solid pharmaceutical composition would obviate the objection.

7. Claims 1-10 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to bicalutamide forms.

8. Claims 23-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.